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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/825,992
Filing Date: April 05, 2001
Appellant(s): TUTUNCU ET AL.

Raymond Mandra
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12-9-08 appealing from the Office action mailed 7-17-08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,284,659	**Cherukuri et al.**	**2-1994**
4,517,205	**Aldrich**	**5-1995**
6,004,538	**Hughes et al.**	**12-1999**
6,306,429	**Bealin-Kelly**	**10-2001**
6,099,880	**Klacik et al.**	**8-2000**
WO97/06695	**Hanke**	**2-1997**
WO99/59427	**Le et al.**	**11-1999**

National Institutes of Dental and Cranofacial Research, NIH Publication, June 1999 ("the NIH publication")

(9) Grounds of Rejection

1. Claims 1-5, 7-8, 10-11, 13-14, 17, 20, 23-24, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al.

Cherukuri et al disclose encapsulated flavor with bioadhesive properties. The compressed confectionary provides controlled release of the flavor and a unique mouth feel by using bioadhesive. The compressed tablet is characterized by discrete phases contained within. See Figure 5 and 6 wherein both phases 1 and 2 have a surface on the exterior of the product.

The compressed tablet include: (a) a first flavor ingredient present in an amount from about 0.1% to 0.5% by weight of a hydrophilic composition with which it is intimately bound to provide instantaneous delivery of the active ingredient or flavor; and (b) a second flavor ingredient present in an amount of from about 3% to 30% by weight of a hydrophobic encapsulating composition containing a bioadhesive so as to provide delivery of the second flavor ingredient over a extended period of time while both the tablet and encapsulated flavors adhere to the moist areas of the oral cavity.

The confectionary compressed tablet is made of a sugar or sugarless base. See column 8, lines 66-67 and column 10, lines 40-45. Sugars taught include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. See column 9, lines 7-21. Emulsifiers (surfactants) are taught in an amount of 2-7%. See column 8, lines 40-55.

Cherukuri also teaches that in addition to encapsulated flavor ingredients, a bio-effecting agent such as breath fresheners, breath deodorants, *antigingivitis agents*, and combinations thereof may also be used. See column 7, lines 30-45.

Table II, example III discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor. This shell region reads on instant "salivation region" since this region contains the bio-effecting agent (the breath freshener). The core comprises 40.32% fat encapsulation material of Table I and 59.68% of a diluent. Table I discloses a fat encapsulation containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. This

core region read on instant “oral comfort region” since this phase predominantly comprises lipids. Cherukuri teaches the diluent may be selected from lactose (sugar), microcrystalline cellulose, starch, talc, sorbitol, mannitol, xylitol, maltitol, xylitol, other sugar alcohols or sugars. See column 8, lines 60-65. Note that this diluent reads on Appellant’s confectionary base of the oral comfort region. The tablet is made by mixing each respective composition with the respective components separately and then the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Although Cherukuri teaches the use of bioeffecting agents in the shell portion, Cherukuri does not teach the specific use of an acidulent in the shell portion.

Le teaches co-processed comestible, confectioneries, pharmaceuticals, and dentifrices comprising acid and water-soluble crystalline compounds. Le teaches that the prior art conventionally uses acidulents in comestible for a variety of reasons. For instance, acidulents may be used to increase saliva production for the treatment of xerostomia and dry mouth; the use of acids to soften plaque on teeth; as flavor enhancers to improve the release of flavor in confectionary products such as hard candies. See page 1. Le teaches the acidulent may be inorganic or organic acids including phosphoric acid, citric acid, malic acid, succinic acid, fumaric acid, ascorbic acid, etc. see page 5, lines 13-25. The acidulent is utilized in an amount of 0.2% of the entire composition (note example 4 in combination with Table 2 formulation wherein the acidulent is 5.5% of the coprocessed formulation and the coprocessed formulation is 3.75% of the composition)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Cherukuri et al and Le et al and utilize an acidulent as the bio-effecting agent in the shell portion of Cherukuri's composition. Firstly, one would have been motivated to do so with a reasonable expectation of success since Cherukuri teaches the use of bio-effecting composition in the composition; thus a skilled artisan would have been motivated to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth or reduce plaque on the teeth. A skilled artisan would have reasonably expected success since Cherukuri teaches various bio-effecting agents may be used including antigingivitis agents and Le teaches the acids reduce plaque, i.e. having an antigingivitis activity. Secondly, one would have been motivated to utilize an acidulent in the shell portion since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. Therefore, a skilled artisan would have been motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the hydrophilic portion (shell portion).

With regard to claim 14, the manipulation of the concentration of emulsifier in the core composition of example III is considered to be obvious to one of ordinary skill. The examples utilize a range of 5%; however one would have been motivated to utilize the

instant range of 0.5-4% since Cherukuri teaches the emulsifier may be utilized in a range of 2-7%. Therefore, the range taught by Cherukuri overlaps the instant range.

2. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/59427 to Le et al in further view of Aldrich (4,517,205).

The disclosures of Cherukuri and Le have been set forth above.

The references do not teach the instant method of making the confectionary product.

Aldrich teaches a method of co-depositing two component hard candy in a mold cavity that produces two distinct areas. See column 2, lines 15-30 and Figures. The method provides an efficient method that is readily adaptable to commercial production of candies with two components. See column 2, lines 5-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and simultaneously deposit the two distinct regions in a mold cavity. One would have been motivated to do so since Aldrich teaches this it is an efficient method that is easily adaptable for commercial production of candies comprising two-components such as a shell portion and core portion.

3. Claims 15-16, 21, 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al in further view of Hughes (6,004,538).

The disclosures of Cherukuri and Le have been set forth above.

The combination of references is lacking the use of an acidulent and the cooling compound specifically.

Hughes teaches an oral composition in various forms including candies. Hughes teaches dental hygiene preparations typically contain antiplaque and/or antitartar agents, as well as antimicrobial agents and flavorants. Hughes teaches antimicrobial action could affect plaque formation by either reducing the number of bacteria in the mouth/dentures or by killing those bacteria trapped in the film to prevent further growth and metabolism. Flavorants may alleviate the problem of bad breath via a deodorizing action. Hughes teaches some antimicrobial agents, such as menthol, also serve as breath deodorizers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize menthol as the flavorant taught in Cherukuri's shell. One would have been motivated to do so since Hughes teaches menthol not only serves as a flavorant but it reduces plaque on the teeth due to its antimicrobial action and it reduces bad breath. Therefore, a skilled artisan would have been motivated to specifically utilize menthol as the flavorant in the shell portion for its various advantageous functions. Moreover, one would have specifically utilizes menthol in the shell area specifically since the shell area

comprises the bioeffecting agents. Further, Le teaches the use of acids to soften plaque on the teeth and thus a skilled artisan would have been motivated to additionally utilize menthol for its additive effect.

4. Claims 1-5, 7-8, 13-18, 23, 29, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695.

Bealin-Kelly teaches a confectionary composition comprising cooling and warming regions, which are in distinct and discrete regions. Bealin-Kelly teaches that various configurations may be utilized including a centre-filled drop that provides a sequential release of the compositions or a configuration that provides differential release profiles as described in WO97/06695, which is incorporated by reference. See column 2, lines 10-25.

Bealin-Kelly teaches sugar base for a hard candy shell comprises from about 30% to about 85% glucose syrup and from about 15% to about 70% sucrose. Alternatively, a sugar-free base maybe used for the shell including bulk sweeteners such as isomalt, maltitol and sorbitol. Isomalt and maltitol are preferred. See column 6, lines 1-15. The "filling" is made of 50-75% of bulk sweetener and may be made of sugar free composition such as sorbitols. See column 5, lines 40-45. Phospholipids such as lecithin are used in an amount of 0.001-1%. See column 5, lines 20-25.

Example 1 teaches a composition comprising a candy containing 49.37% sucrose, 49.37% glucose syrup, 0.27% lemon oil, 0.08% menthol (cooling compound), and 0.91% citric acid (acidulent). The filling contains 84.3% high fructose corn syrup,

15% glycerin, 0.02% lecithin (surfactant), 0.314% lemon oil, and 0.16% color. See example 1. Note that the shell reads on the instant salivation region and the fill reads on the oral comfort region. The regions are mixed separately and co-extruded.

Bealin-Kelly does not exemplify the instant configuration.

WO 97/06695 teaches a confectionary product comprising a coolant composition and flavoring composition in separate and distinct regions. The composition may take various form including hard candies wherein the distinct regions are in separate layers. See page 3. WO '695 teaches using molds in which the respective composition is placed and each composition has a surface on the exterior of the product. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made Bealin-Kelly and WO '695 and utilize a configuration wherein the respective compositions are in separate layers rather than a "centre-filled drop". One would have been motivated to do so with a reasonable expectation of success since Bealin-Kelly incorporates the teachings of WO '695 and suggests various configurations may be used including the configuration taught in WO '695, i.e. distinct regions.

5. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695 in further view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999.

The disclosures of Bealin-Kelly and WO '695 have been set forth above.

Although Bealin-Kelly teaches the use of the confectionary product for providing soothing properties, Bealin-Kelly does not specifically teach the use of the product to treat xerostomia.

The NIH publication teaches xerostomia (dry mouth) is caused by several factors such as the side effects of medication, diseases, chemotherapy, etc. The symptoms include sticky, dry mouth, trouble chewing, swallowing, tasting, and a burning feeling in the mouth, a dry feeling in the throat, cracked lips, a dry tongue, and mouth sores. The publication teaches methods of treating xerostomia include, chewing sugarless gum or sucking on sugarless gum to stimulate saliva flow. Candies that have citrus, cinnamon, or mint are good choices.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and Bealin-Kelly's composition to treat xerostomia. One would have been motivated to do so since Bealin-Kelly teaches a sugarless confectionary product containing citrus flavors and menthol and the NIH publication teaches sucking on sugarless candies, particularly ones that contains citrus and mint, treat xerostomia. Furthermore, a skilled artisan would have expected success since Bealin-Kelly teaches the confectionary provide soothing properties and the symptoms of dry mouth include a burning feeling in the mouth and dry feeling in the mouth, and mouth sores.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695 in further view of US patent 6,099,880 to Klacik et al.

The disclosure of Bealin-Kelly and WO '695 have been set forth above.

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method is a simple method of forming distinct regions. See column 1, lines 30-50.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

(10) Response to Argument

1. Claims 1-5, 7-8, 10-11, 13-14, 17, 20, 23-24, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al.

Appellants argue that unlike the instant confectionary product with regions each having a surface on the exterior of the product, the product of Cherukuri (fig. 5) is center filled with two the regions i.e., shell and core. It is argued that the office fails to articulate a reason why one of ordinary skill in the art would have started with an embodiment of figures 5 and 6 of Cherukuri. Appellants' arguments are not persuasive because the argued core-shell embodiment is only a preferred embodiment of Cherukuri, which is different from the product of fig. 5 of Cherukuri. Fig. 5 shows a product with discrete phases to the exterior.

Appellants argue that examiner did not allege that Cherukuri teaches the use of any compound for saliva creation, a product to promote saliva or fat encapsulation to lubricate, coat or moisten an oral cavity. In response to this argument, the rejection relies on the teachings of Le for acidulents and not on Cherukuri reference. It is argued that Le only mentions the use of an acid in a chewing gum to increase saliva production in related patents but fails to actually teach a chewing gum for removing or preventing the deposition of plaque on teeth. It is argued that the combination of the references should yield predictable use of the prior art elements according to their established functions. However, the argument is not persuasive because the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). Prior art teachings are not limited to preferred embodiments and instead should be considered as a whole. In the instant case, Le does recognize the

property of acidulents for increased saliva production. Le teaches acidulents are commonly used in edible and dentifrice products for a variety of reasons including (1) increasing saliva production to treat xerostomia or dry mouth; (2) for use in exercising; (3) to soften plaque; and (4) as flavor enhancers and to improve the release of flavors in confectionary products. Accordingly, salivation would have been an obvious result with the incorporation of the acidulents of Le in the composition of Cherukuri, if one desired to treat xerostomia and dry mouth or reduce plaque on the teeth.

Appellant argues that acids only reduce plaque in combination with an abrasive. Appellant argues that edible acids do not have any effect on plaque or any antigingivitis activity and that Cherukuri teaches suitable gingivitis agents such as thymol, menthol etc., none of which are acids. In this regard, appellants refer to the Declaration under 37 CFR 1.132 submitted by Dr. Stephen Moss (submitted on 5-5-08). It is also argued that reduction of plaque is not recognized as a treatment of gingivitis and that the substitution of an acid taught in Le for a "bio-affecting agent" in Cherukuri is not a reason to combine the prior art. It is argued that a connection between removal of plaque and the treatment of existing gingivitis has not been established.

Rule 132 Declaration of Dr. Stephen Moss states that Le describes a method of removing plaque but only using a combination of an acid and abrasive. The Rule 132 states that neither Le nor Muhler disclose the use of acid as an anti-gingivitis agent and in Dr' Moss's experience, acids are not used as anti-gingivitis agents. Dr. Moss states "I do not believe that acid by itself would remove plaque from teeth or act as an antigingivitis agent, I do not believe that a desire to reduce plaque on teeth would have

been a valid reason to combine an acid according to Le in a tablet according to Cherukuri."

Appellant's arguments and Rule 132 Declaration of Dr. Moss have been fully considered. They are not persuasive because Cherukuri requires antigingivitis agents and breath odor control agents (claim 7) in their confectionary compositions, both of which are related to the oral hygiene. The declaration is insufficient to overcome the rejections. First, it is noted that the Rule 132 Declaration is an opinion Declaration and has been given little weight since it does not provided any factual evidence. Second, the above rejection contained several advantages of using acidulents other than the function of reducing plaque. Le teaches acidulents are commonly used in edible and dentifrice products for a variety of reasons including (1) increasing saliva production to treat xerostomia or dry mouth; (2) for use in exercising; (3) to soften plaque; and (4) as flavor enhancers and to improve the release of flavors in confectionary products. Further, Cherukuri suggests the use of antigingivitis agent and Le teaches acids "soften plaque". It is noted that the instant claims do not exclude combinations of active agents and thus the claims do not exclude Le's use of an acidulent and abrasive to treat plaque and thereby preventing or treating gingivitis.

Appellants argue that the Declaration of an expert that acid is not an antigingivitis agent has not been properly considered. However, even assuming that softening plaque does not help treat gingivitis and does not act as an antigingivitis agents, there are other reasons for using acidulents. For instance, Cherukuri teaches the shell portion, which reads on the salivation region, releases the active agent or flavor instantaneously. Le

teaches acidulents are known to improve the release of flavors. Thus, a skilled artisan would have been motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the hydrophilic portion (shell portion).

Appellants argue that including the acidulent as a flavor or active release is not a reason to arrive at the instant invention. It is argued that it is not a valid reason to segregate lipids and acids in macroscopic regions because according to Cherukuri both regions contain a flavor and Le teaches distribution of acid throughout the product. Appellant's arguments are not persuasive because Cherukuri teaches that the single flavor may be present in the compressed tablet combined with either hydrophobic or a hydrophilic system (col. 5, L 41-49) and thus the flavor need not be present through out the product of Cherukuri. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellants argue that the action applies references without regard to the stated functional purpose of the invention i.e., useful for dry mouth. However, Cherukuri teaches the use of bio-effecting active to release in the oral cavity and Le teaches acidulents are used to treat xerostomia (dry mouth). Thus, if a skill artisan wanted to

treat xerostomia, one would have substituted Cherukuri's breath freshener in the example with an acidulent.

Claim 17

Appellants argue that Independent claim 17 is directed to the method of manufacturing the product of the present invention. The Examiner has rejected claim 17 over Cherukuri in view of Le without identifying where Cherukuri or Le discloses (1) an acidulent with a sugar base or a sugarless base, as Claimed, and (2) a lipid or surfactant in a sugar base or a sugarless base, and then (3) forming a hard candy from the respective bases. It is argued that the claimed invention cannot be found obvious absent a showing that these teachings are in the prior art.

Appellants' arguments are not persuasive because Cherukuri teaches the preparation of the confectionary product with sugar or as a sugarless product (col. 8, L 66-col. 752). Cherukuri lists a number of sweeteners that can be used in place of natural sweeteners such a sugar. Cherukuri also teaches including a sweetener in the first phase (col. 10, L 40-45). While instant claims recite a sugarless base, any of the components taught by Cherukuri in the second phase i.e., gums, microcrystalline cellulose, calcium carbonate etc., (col. 8, L 17-33 and col. 8, L 55-65) read on the sugarless base of the instant claims. Further, to incorporate the sweeteners in an appropriate phase of the tablet of Cherukuri would have been within the scope of a skilled artisan (see Cherukuri, col. 10, L 4-10).

Claims 18 and 19

Appellants argue that claims 18 and 19 are not obvious over Cherukuri, Le and Aldrich because Cherukuri is directed to compressed tablets (see abstract), and Le is primarily directed to products such as toothpaste and chewing gum (see Examples), with only passing reference made to other food products. It is argued that though Aldrich is alleged to show the method of making a hard candy recited in claims 18 and 19 (Office Action, page 9), one of ordinary skill in the art, starting from the disclosure of Cherukuri and Le, would have not have been directed to formulate a hard candy according to the method of Aldrich, using the ingredients of Cherukuri and Le.

Appellants' arguments are not persuasive because the though Le primarily teaches tooth paste and a chewing gum, Le also recognizes confectioneries such as hard candy (page 1, Related art). As explained in the preceding paragraphs, the teachings of prior art are not limited to preferred embodiments and should be considered as a whole. Therefore, a skilled artisan would have readily recognized that the compositions of Le include not only chewing gums but also candy and other confectioneries.

Claims 15-16, 21, and 28

Appellants argue that claims 15-16, 21 and 28 require the combination of an acidulent and a cooling compound in the salivation region and that the rejection of claims as obvious to include a cooling compound in the shell region of Cherukuri because (1) Hughes teaches that menthol is both a flavorant and reduces plaque, (2) Le teaches the use of acids to soften plaque on teeth (Office Action page 10), plainly relies

on hindsight. Appellants argue that Cherukuri and Le suffer from the deficiencies (discussed supra) and that Hughes does not remedy the deficiencies. It is argued that there is no teaching in the references of an acid and cooling compound used together, and even if they were combined there is no disclosure in the prior art of these ingredients being used together in a salivation region.

Appellants' arguments regarding the teachings of Cherukuri and Le have been addressed above and incorporated herein. The teachings of Hughes are in the same field of endeavor i.e., candy product and also for oral hygiene (antiplaque) and are hence analogous to the teachings of Le and Cherukuri. Accordingly, Hughes provides the requisite motivation to employ the flavorants such as menthol in the composition of Cherukuri because menthol not only serves as a flavorant but it reduces plaque on the teeth due to its antimicrobial action and it reduces bad breath. Further, Le teaches the use of acids to soften plaque on the teeth and thus a skilled artisan would have been motivated to additionally utilize menthol for its additive effect.

Claims 1-5, 7-8, 13-18, 23, 29, and 31 Are Not Obvious over Bealin-Kelly in View of Hanke

Appellants argue that based on the identified prior art, it would not have been obvious to develop a confectionery product to promote salivation, and a product useful to treat salivation does not result inherently from the combinations proposed by the Examiner. It is argued that Bealin-Kelly is directed to "center-filled confectionery compositions, especially liquid centre-filled confectionery." (Bealin-Kelly, col. 1, lines 7-9). The Examiner concedes that Bealin-Kelly "does not exemplify the instant

configuration," and relies on Hanks (incorporates Bealin-Kelly by reference) for the discrete regions on the surface. Appellants argue that Bealin-Kelly does not disclose a lipid "selected from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof," as set forth in the present claims and that the Examiner's statement that "Bealin-Kelly teaches an oral comfort region and a salivation region," (OA, page 12, line 8) is not supported factually.

Appellant's arguments have been fully considered but they are not persuasive. Appellants' attention is directed to column 4, lines 55-58 in which Bealin-Kelly teaches, "The filling can be a solid, particularly a powder, or a liquid, including forms of intermediate consistency such as a paste or a gel." Therefore, the term "liquid" includes viscous consistency. Thus, the instant configuration is merely a design choice and clearly Bealin- Kelly suggests other configurations including those taught in WO 97/06695. WO '695 teaches confectionary products have distinct and discrete regions wherein both regions can be a surface on the exterior of the product. If appellants is asserting that the paste or gel cannot be designed in the claimed configuration due to its consistency, appellant's attention is directed to Aldrich (US 4,517,205), prior art of record. Aldrich demonstrates it is possible to configure a hard portion and a viscous portion in the instant configuration, i.e. wherein both regions have an exterior surface.

It is argued that at no point does Bealin-Kelly indicate that an ingredient is present in an amount effective to "lubricate, coat or moisten" the oral cavity and that

acidulent in the composition is "effective to aid in the stimulation of the flow of saliva," as claimed. It is argued that what the Examiner apparently alleges is that once a rationale is arrived at to combine these ingredients, then the claimed results must inherently form a treatment for xerostomia. Appellants also argue that both Bealin-Kelly and Hanke are directed to cough/cold medicines and not xerostomia, the differences of which have been amply demonstrated (Rule 132 declaration of Kevin Stanton, 5-1-2006). It is further argued that the purpose of the product design according to Bealin-Kelly and Hanke is to provide sequential release profiles to the components that are separated in discrete regions (see, for example, Bealin-Kelly Abstract and col. 1, lines 50-52; Hanke, page 3, line 7 and page 11, lines 1-16), which is completely contrary to the result achieved with the claimed invention, in which the oral comfort ingredient soothes the effect produced by the concentrated acidulent, so that both sensations are in the mouth at about the same time.

Appellants' arguments are not persuasive because Bealin-Kelly teaches the incorporation of sweeteners in the composition, which possess the claimed characteristics i.e., "lubricate, coat or moisten" the oral cavity and "aid in the stimulation of the flow of saliva". Additionally, Bealin-Kelly teaches an oral comfort region and a salivation region. Therefore, results showing the unexpectedness of the acid and lipid/surfactant region is not persuasive since the prior art teaches the combination of both. Further, with respect to the treatment of Xerostomia, it is to be noted that instant claim 20, directed to a method of treating xerostomia, is not rejected under this section. With respect to the design choice, instant rejection is not based on Bealin-Kelly alone

and instead over a combination of Bealin-Kelly and WO '695. WO '695 teaches confectionary products have distinct and discrete regions wherein both regions can be a surface on the exterior of the product. Further, Aldrich also suggests a hard portion and a viscous portion in the instant configuration, i.e. wherein both regions have an exterior surface. With respect to the sequential release profile of Hanke as opposed to the simultaneous release profiles, Instant claims do not recite any release profiles and moreover, as explained previously the motivation to alter the design i.e., discrete regions having an exterior surface containing different components comes from the teachings of WO 695 and Aldrich. Accordingly, a skilled artisan would have expected to obtain simultaneous release of the components from the two separate regions i.e., an oral comfort region and a salivation region of Bealin-Kelly because the Aldrich and WO 695 have been cited for the teachings of discrete regions and not for the components of the discrete regions.

Claims 20 and 21

Appellants argue that the Examiner's argument does not motivate the treatment of xerostomia with the claimed product because it was known in the prior art that sucking on a lozenge might provide some relief from xerostomia (see the specification at page 2, lines 23-29) and the NIH publication simply reflects what is stated in the specification. It is argued that the Background of the Invention also makes clear that a need existed in the art for more effective products specifically adapted to the treatment of xerostomia. It is argued that the claimed invention is a treatment of xerostomia using a confectionery product having a specified configuration, and the nonobviousness of

that invention has not been addressed in the rejection. It is argued that to demonstrate that the present invention provides a treatment for xerostomia that can be distinguished from the relief provided by sucking on a generic candy, Appellants previously provided marketing data and analysis in the form of a Declaration by Donald Mayer (Exh. E-5), which is believed to show that consumer reaction to the product registered an unusual awareness on the part of consumers of the product functionality as a treatment of dry mouth, as opposed to merely registering consumer satisfaction, for example (see Exh. E-5, paragraphs 10-11).

Appellants' arguments are not persuasive because appellants admit that sucking on a lozenge might provide relief from xerostomia. Further, it is noted that Bealin-Kelly teaches an oral comfort region and a salivation region; thus providing salivation and obviously treats xerostomia. The results showing the unexpectedness of the acid and lipid/surfactant region is not persuasive since the prior art teaches the combination of both. If appellants' argue that the unexpected advantage of the instant composition in treating xerostomia is because of the separate phases of the salivation and the comfort region, then WO 695 and Aldrich references suggests such separation, which have been cited in combination with Bealin-Kelly reference. With respect to the Rule 132 Declaration of Donald Mayer, the Declaration provides the consumer call data in connection with AQUADROPS. However, the Declaration of Mr. Mayer is insufficient to overcome the rejections because the Declaration refers to Aquadrops but does not describe the exact composition of the product is not given. Thus, it is not possible to

make a conclusion of unexpectedness and ascertain if the claims are commensurate in scope without the specifics of the composition.

Claim 19

Appellants argue that Klacik is not believed to overcome the deficiencies of Bealin-Kelly and Hanke and therefore Claim 19 should be allowable for the same reasons as argued above in connection with the independent method claim 17. It is argued that Klacik is applied against the claims as it relates to the mold configuration used in the method of making and that one would only utilize a mold according to Klacik if one had just decided on a configuration where discrete regions are present on the surface of the product. Appellants argue that the layered and center-filled configurations of Hanke and Bealin-Kelly are designed to obtain sequential release profiles, so that one of ordinary skill in the art would have had no reason to arrive at that configuration, and the use of the mold described in Klacik would not have been obvious.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The rejection admits that Bealin-Kelly lacks separate regions and that WO 695 that teaches separate regions also lacks a ridge to separate the components. The teachings of Klacik have been cited for the missing element i.e., a mold having a ridge so as to separate the regions in the candy. The teachings of Klacik constitute analogous

art because the reference teaches compositions containing the same ingredients i.e., sugar, sugar alcohol, flavors, oils etc., all of which are also taught or suggested by Bealin-Kelly and also WO '695. Thus, it would have been obvious to modify the candy composition of Bealin-Kelly to separate the two regions (suggested by WO '695) and also include a ridge separating the regions (suggested by Klacik) and with an expectation to maintain the distinction of the separated regions.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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